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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,015	01/14/2004	Axel Riedel	1/1443US	3296

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
05/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/757,015	**Applicant(s)** RIEDEL ET AL.	
	Examiner Leslie A. Royds	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *10 May 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): the rejection of claims 1, 8 and 18-32 under 35 U.S.C. 102(b).
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1 and 8-35*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
    See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Leslie A. Royds
Patent Examiner
Art Unit 1614

18 MAY 2007

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant requests reconsideration of the present application in light of the remarks presented in the papers filed May 10, 2007.

Applicant traverses the rejection under the enablement requirement of 35 U.S.C. 112, first paragraph, stating that: (1) the Examiner's allegation that the term "prevent" requires absolute success is contrary to what one of ordinary skill in the art would understand the term to mean in the context of the present invention, (2) the reasoning in Ex parte Cho is clearly relevant here because it concludes that compounds shown to be useful for treating conditions once they exist would be expected to be effective in preventing these conditions if administered before the onset of the condition, (3) conclusory statements that the situations are different without explaining why these alleged differences result in a different outcome does not meet the Examiner's obligation of providing reasoning for the rejection, (4) the Office has been repeatedly reversed for rejecting claims for a lack of enablement when the compounds have demonstrated pharmaceutical and biological activity and (5) it is very likely that the Board would follow the reasoning of Ex parte Cho in the instant case.

Applicant's traversal of this rejection has been fully and carefully considered in its entirety, but fails to be persuasive.

First, regarding Applicant's argument that the interpretation of the term "prevent" as requiring absolute success is improper, Applicant is reminded that the specification sets forth absolutely no definition of what Applicant intends for the term "prevent" to mean and, thus, in accordance with the MPEP at Sect. 2111, examination of the claimed terminology must be made with the broadest reasonable interpretation consistent with the specification. Absent any direction in the specification, the Examiner relies upon the broadest interpretation of the term "prevent" as understood by one of ordinary skill in the art at the time of the invention. Applicant's allegations that the skilled artisan would not interpret such a term as, at least in its broadest embodiment, encompassing absolute success is completely unsupported by any evidence and, therefore, amounts to no more than an allegation without factual support. Applicant is reminded that, in accordance with MPEP Sect. 716.0[c][R-2](II), "The arguments of counsel cannot take the place of evidence in the record." Accordingly, these arguments are clearly not persuasive.

Second, Applicant continues to allege that compounds effective to treat a disease would logically be effective in preventing said disease and insists that Ex parte Cho is relevant in the instant case. However, this is again not persuasive because the assertion of a lack of enablement in Ex parte Cho was based upon a number of factors, including the breadth of compounds claimed versus those that had been shown to actually possess biological activity and the breadth of diseases claimed to be treated or prevented using such a broad genus of compounds. This is clearly not the same as the instant case. Applicant is claiming a discrete combination of two very well-known chemical entities (i.e., telmisartan and simvastatin) for various methods of treatment or prevention. The instant enablement rejection is set forth SOLELY on the embodiments of prevention because Applicant has failed to give any guidance whatsoever as to what population of patients would be reasonably expected to be at risk for developing the claimed diseases and, thus, would be in need of prevention. In other words, Applicant's reliance on the conclusion in Cho that compounds useful for the treatment of a disease must, therefore, be useful for preventing the same prior to onset of the condition does not address the fact that Applicant has obviously failed to provide any guidance as to how those patients in need of prevention of such a condition could be identified if they are not showing any proclivity to developing such a condition without undertaking a burden of undue experimentation. Accordingly, repeated reliance upon a non-precidential court decision fails to raise any issue of material fact in the instant case and is, therefore, not persuasive.

Third, in response to Applicant's arguments that the Examiner has not provided reasoning for the instant rejection, Applicant's attention is directed to the previous Office Actions of March 30, 2006 and November 26, 2006, where such reasoning is set forth and does not rely upon "conclusory statements" as alleged by Applicant or a "secret objection" to patentability "harbored by the Examiner" as also alleged by Applicant at page 3 of the remarks.

Fourth, Applicant relies upon the fact that the Office has been repeatedly reversed for rejecting claims as lacking enablement when compounds have demonstrated pharmaceutical and biological activity as evidence that the instant rejection is improper. However, Applicant is reminded that the present rejection against the amended claims of September 19, 2006 has only been set forth insofar as the claims lack enablement for the embodiments of prevention of the claimed diseases. The activity of the claimed combination in the treatment of such diseases is not disputed and was not asserted to lack enablement. Please reference page 2 of the previous Office Action of November 27, 2006.

Lastly, Applicant's statement that the Board would likely follow the reasoning of Ex parte Cho is Applicant's conjecture and conspicuously fails to address the facts in the instant case and, accordingly, is not persuasive.

Applicant's arguments against the application of the De Gasparo et al. reference under 102(b) will not be further addressed herein because the rejection has been withdrawn.

Applicant traverses the rejection of claims 1 and 8-35 under 35 U.S.C. 103(a), stating that De Gasparo et al. fails to teach the claimed combination of telmisartan and simvastatin anywhere in the reference and, further, fails to teach or suggest that telmisartan increases the expression of genes regulated by the PPARgamma receptor, which is the reason for combining telmisartan with simvastatin. Applicant additionally asserts that none of the secondary references disclose, suggest or hint at telmisartan combinations with statins.

Applicant's traversal of this rejection has been fully and carefully considered in its entirety, but fails to be persuasive.

Applicant's attention is directed to pages 8-10 of the previous Office Action dated November 27, 2006, where such remarks have already

been fully considered and addressed. For brevity of the record, the remarks set forth at pages 8-10 of the previous Office Action will not be repeated herein, but are hereby incorporated by reference.

Applicant states that filing of a Terminal Disclaimer will be considered against the cited copending application(s) if the instant claims are found allowable and if Applicant determines that such an application(s) poses a double patenting issues at that time.

Insofar as the instant claims are not in condition for allowance, and further that the instant claims and the copending claims raise an issue under the judicially created doctrine of obviousness-type double patenting for the reasons already set forth in the previous Office Action dated November 27, 2006 at pages 10-14, the rejections are maintained.

For these reasons, the claims remain rejected for the reasons of record set forth in the final rejection of November 27, 2006, of which the entirety of said reasons are herein incorporated by reference.

18 MAY 2007

5/22/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER